

Docket No.: AB-185U

REMARKS/ARGUMENTS

The Office Action dated January 9, 2006 has been carefully considered. Applicant has amended Claims 1, 4, 14, 17 and 18. No new matter has been added. Support for the amendments made are found in various parts of Applicant's specification.

Claims 1, 2, 5-11, 14, 17 and 18 rejected under 35 U.S.C. 102(b)

Claims 1, 2, 5-11, 14, 17 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (U.S. Pat. No. 6,214,016, hereinafter referred to as "Williams"). This rejection is respectfully traversed.

Applicant's Claim 1, as amended, recites:

Claim 1 A stylet for use with a medical stimulating lead, the stylet comprising: an outer covering, made of a metal outer covering material; and an inner core, made of inner core material, the inner core inside the outer covering, wherein the outer covering material and inner core material have different elastic and buckling properties.

Applicant's Claim 1 recites a stylet that has an "outer covering" and "an inner core" of different "elastic and buckling properties". Williams does not provide a stylet with this construction or configuration.

Docket No.: AB-185U

The Examiner has noted that "Williams disclosed a stylet (42 and 46), comprising an outer covering (44), and inner core (46), and the outer and inner portions have different elastic and buckling properties (col. 5, line 37 and col. 6, line 8)." [See, Office Action, page 2, paragraph 4.] Element 46 in Williams is indeed the stylet but element 42 is not a stylet or part of a stylet, but is, instead, an outer tubular member as referred throughout Williams' specification. This outer tubular member 42 is separate from the stylet 46 by necessity and the outer tubular member is not any part of the stylet. The outer tubular member 42, the inner tubular member 44, and the innermost member 46 (the stylet) are separate because they are "slidably movable within each other and are selectively positionably." [See, Williams, column 6, lines 60-63, and also Figure 6.] The outer tubular member 42 and the inner tubular member 44 each have an axial channel running though and are therefore cannulas.

The innermost member 46 is, by itself, the stylet. Williams, column 6, line 7, states, "Referring to FIG. 11, the innermost member 46, or stylet,..." Williams describes further the innermost member 46 (the stylet), in column 6, lines 7-26. Williams never states that the stylet itself should have an outer covering and inner core. Instead, Williams teaches that, "[t]ypically, the innermost member 46 is a straight, solid wire fabricated from a metal such as tungsten or stainless." [Williams, column 6, lines 8-10.] This innermost member 46 (stylet) is "slidably movable within the inner tubular member 44." [Column 6, lines 17-18.] Thus, Williams teaches a conventional stylet, which is solid and made of the same metal throughout.

As explained throughout Williams' specification, all of the elements must be slidable relative to each other (and therefore separate from each other) because

Appl. No. 10/635,091

Amendment A dated April 10, 2006

Reply to Office Action of January 9, 2006

Page 6 of 10

Docket No.: AB-185U

Williams' device permits the stylet to curve or bend through tissue such as brain tissue. By contrast, in Applicant's Claim 1, the stylet is formed with an outer covering and a inner core, and these parts are integral to the stylet. Because Williams fails to teach a stylet having an outer covering and an inner core, Applicant's Claim 1 is not anticipated.

Claims 2 and 5-11 are dependent on Claim 1. Although there may be other reasons why Williams does not anticipate these dependent Claims 2 and 5-11, they are at least allowable because they depend on Claim 1, which is allowable.

Independent Claim 14 was also rejected as anticipated by Williams. Claim 14 recites a stylet that has "an outer covering; and an inner core", the outer covering substantially more flexible than the inner core. Williams does not teach such a stylet having an outer covering and inner core, as previously discussed and thus Claim 14 is not anticipated by Williams. Claim 17 is not anticipated, at least, although not necessarily only because of, its dependency on Claim 14.

Independent Claim 18 was rejected as anticipated by Williams. Claim 18 is a lead system that includes a stylet having an outer covering and an inner core material. As discussed, Williams does not discuss or teach a stylet constructed in that manner. Thus, Claim 18 is not anticipated.

Claim 13 rejected under 35 U.S.C. 102(b) or 103(a)

Claim 13 was rejected under 35 U.S.C. 102(b) as anticipated by Williams or alternatively 103(a) as obvious over Williams. These rejections are respectively traversed.

Appl. No. 10/635,091
Amendment A dated April 10, 2006
Reply to Office Action of January 9, 2006

Page 7 of 10

Docket No.: AB-185U

Claim 13 is allowable by virtue of its dependence on Claim 1, which is in condition for allowance. There can be no anticipation or obviousness because Williams does not teach or suggest a stylet that has an integral outer covering and an inner core. Williams, in column 6, line 46, merely indicates that the entire stylet may be made from a solid material of Ni-Ti. There is no mention in Williams of a stylet with the elements: an outer covering and an inner core.

Claim 3, 4, and 12 rejected under 35 U.S.C. 103(a)

Claims 3, 4, and 12 were rejected under 35 U.S.C. 103(a) as unpatentable over Williams. This rejection is respectfully traversed. Williams' Figure 10 depicts a cross-section of an inner tubular member 44 with an axial channel or bore 70. Inner tubular member 44 is not a stylet. It is more properly referred to as a cannula because it has a channel. The only stylet mentioned by Williams is the innermost member 46. Applicant's Claim 4 concerns a stylet that includes a tube and inner core, however, the "tube" describes the geometric shape of the outer covering. The stylet is comprised of a piece that is initially in the form of a hollow tube before the stylet is assembled with the core. But after assembly, the inner core is placed within the tube, and the two pieces are non-separable and form a stylet. Claim 4 has now been amended to clarify that the tube and core are non-separable, and hence non-movable relative to each other and comprise the stylet. (In addition, Claim 17 has also been similarly amended to clarify that the tube and core are non-separable and form the stylet.) Claims 3, 4 and 12 are all dependent on independent Claim 1, which is believed to be in condition for

Appl. No. 10/635,091
Amendment A dated April 10, 2006
Reply to Office Action of January 9, 2006

Page 8 of 10

Docket No.: AB-185U

allowance. For that reason alone, although not necessarily the only reason, Claims 3, 4, and 12 are believed to be allowable.

Claim 15, 19, and 20 rejected under 35 U.S.C. 103(a)

Claims 15, 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Stoy et. al. (U.S. 5,217, 026, hereinafter referred to as "Stoy"). In response to this rejection, Applicant has amended independent Claims 14 and 18, upon which claims 15, 19 and 20 depend and, in addition, independent Claim 1 has been amended, to add the limitation of a *metal* outer covering. Stoy mentions a stylet with an outer covering of hydrogels, fluopolymers (Teflon® material) and specific plastics, such as polypropylene and polyethylene, but not metal.

Because Stoy does not disclose a stylet having an outer covering that is metal, no combination of Williams and Stoy can now yield an outer *metal* covering and an inner core as prescribed in Applicant's Claims 15, 19 or 20 or, for that matter, any Claims 1-20. Claim 15 depends on independent Claim 14, and for at least this reason, Claim 15 is in condition for allowance. Claims 19 and 20 depend on independent Claim 18, and thus, Claims 19 and 20 are believed in condition for allowance. The 103(a) obviousness rejection to Claims 15, 19 and 20, is thus overcome.

By way of this Amendment A, Claims 1, 4, 14, 17 and 18 have been currently amended. Claims 1-20 are currently pending. As the total number of independent and dependent claims has not been changed with entry of this Amendment A, no additional fees are believed due. Nonetheless, please charge any required fees or credit overpayment to Deposit Account Number 50-0648.

Appl. No. 10/635,091
Amendment A dated April 10, 2006
Reply to Office Action of January 9, 2006

Page 9 of 10

Docket No.: AB-185U

An early indication of allowability of pending Claims 1-20 is courteously requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,

April 10, 2006

Date

Philip H. Lee

Philip H. Lee

Reg. No. 50,645

Attorney for Applicant

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
25129 Rye Canyon Road
Valencia, California 91355
Fax: (661) 362-1507

Please direct all telephone inquiries to:
Philip H. Lee
Telephone: (661) 362-1964

Appl. No. 10/635,091
Amendment A dated April 10, 2006
Reply to Office Action of January 9, 2006

Page 10 of 10